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| 10/552,951 | 06/22/2006 | William F. Ogilvie | 81723 | 6894 |
| 22342 7590 12/28/2009 FITCH EVEN TABIN & FLANNERY 120 SOUTH LASALLE STREET SUITE 1600 CHICAGO, IL 60603-3406 | | | | |
| EXAMINER | | | | |
| LEVINE, JOSHUA H | | | | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/552,951

Applicant(s)

OGILVIE, WILLIAM F.

Examiner

JOSHUA LEVINE

Art Unit

3774

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 August 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) ___ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ___ is/are allowed.
- 6) ☐ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) ___ is/are objected to.
- 8) ☐ Claim(s) ___ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 October 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/GS/US)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____
- Paper No(s)/Mail Date _____

DETAILED ACTION

Response to Amendment

1. This office action is responsive to the amendment filed on 08/21/2009. As directed by the amendment: claims 1, 7, 9 and 15-16 have been amended, no claims have been cancelled, and no new claims have been added. Thus, claims 1-20 are presently pending in this application.

Response to Arguments

2. Applicant's arguments, see Applicant Arguments/Remarks Made in an Amendment, filed 08/21/2009, with respect to the rejection(s) of claim(s) 1-2, 4-5, 9-10, 12-13 as anticipated by Serhan et al. (7004971) under 102(e) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Pedersen et al. (20030093152).

3. Applicant's arguments, see Applicant Arguments/Remarks Made in an Amendment, filed 08/21/2009, with respect to the rejection(s) of claim(s) 3, 6, 11, 14 as anticipated by Serhan et al. (7004971) under 103(a) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Pedersen et al. (20030093152).

4. Applicant's arguments filed 08/21/2009 have been fully considered but they are not persuasive.

The applicant argues that the disk of Pedersen et al. is designed for replacing damaged

cartilage and is designed to deform leaving it unable to slide upon interfacing concave articular surfaces and rendering its original shape of little importance. The examiner affirms the rejection as Pedersen et al. explicitly teaches that the device is adapted in its shape (structure, paragraph 24) to provide sliding/rotating movement (paragraph 24).

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 9-10, 12-13 rejected under 35 U.S.C. 102(b) as being anticipated by Pedersen (PG Pub No. 20030093152).

7. Regarding claim 9, Pedersen disclosed a surgically implantable prosthesis biarticular disk designed to replace a CMC joint (fingers, paragraph 196) , which implant comprises: an integral disk (figure 14, paragraph 257) which is circular in plan view and has a pair of convex spherical articular surfaces 49 (outer surface, figure 14), each of which is a section of a sphere, and an axial, flaring hole 48 (central passage, paragraph 257) which extends therethrough from articular surface to articular surface to accommodate a flexible cord (ligament, paragraph 42) that is passed through passageways in the metacarpus and the trapezium or other carpal bone, said convex spherical articular surfaces being interconnected at their peripheries by a curved rim surface (figure 14) which is a segment of a spheroid, which disk has a modulus of elasticity similar to cortical bone (10 MPa-50 MPa, claim 50) with each bone sliding on

the respective mating convex articular surface of the disk (sliding/rotating, paragraph 24) while the flexible cord conforms to the flaring surface of the axial hole in the plane of flexion(via circular movement, paragraph 66)

8. Regarding claim 10, Pedersen disclosed that the axial flaring opening is a section of a torus (torus shaped, paragraph 34).

9. Regarding claim 12, Pedersen disclosed that the radius of curvature of transition surfaces between said toroidal surface and said convex spherical surfaces is between about 0.7 and about 3 mm (2mm-60mm, paragraph 52).

10. Regarding claim 13, Pedersen disclosed that the radii of curvature of said pair of convex spherical surfaces are the same (symmetrical, paragraph 34) and wherein said peripheral rim surface is a segment of a sphere (disc shaped, paragraph 257).

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claims 1-6, 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pedersen (PG Pub No. 20030093152) in further view of Farling (4055862).

13. Regarding claim 1, Pedersen disclosed a surgically implantable prosthesis biarticular disk designed to replace a CMC joint (fingers, paragraph 196) , which implant comprises: an integral disk (figure 14, paragraph 257) which is circular in plan view and has a pair of convex spherical articular surfaces 49 (outer surface, figure 14), each of

which is a section of a sphere, and an axial, flaring hole 48 (central passage, paragraph 257) which extends therethrough from articular surface to articular surface to accommodate a flexible cord (ligament, paragraph 42) that is passed through passageways in the metacarpus and the trapezium or other carpal bone, said convex spherical articular surfaces being interconnected at their peripheries by a curved rim surface (figure 14) which is a segment of a spheroid, with each bone sliding on the respective mating convex articular surface of the disk (sliding/rotating, paragraph 24) while the flexible cord conforms to the flaring surface of the axial hole in the plane of flexion(via circular movement, paragraph 66) except for which disk is a graphite core coated with wear-resistant pyrocarbon and once surgically implanted allows the metacarpus to flex relative to the trapezium or other carpal bone enough for useful hand function.

Farling teaches a surgically implantable prosthesis articular disk 20 (tibial plateau, figure 6) with a graphite core (graphitic carbon fiber, column 4 lines 53-54) coated with wear-resistant pyrocarbon (via pyrolytic procedures, column 4 line 54) and once surgically implanted allows the metacarpus to flex relative to the trapezium or other carpal bone enough for useful hand function (see disclosed body parts, column 5 lines 41-42, column 6 lines 1-2). It would have been obvious to one of ordinary skill in the art at the time of the invention to utilize the carbon fibers of Farling for the purpose of providing a material that resists cold flow (column 2 lines 2-3) and retains its geometry under prolonged conditions of exposure to rolling or sliding pressure (column 2 lines 5-7).

14. Regarding claim 2, Pedersen disclosed that the axial flaring opening is a section of a torus (torus shaped, paragraph 34).

15. Regarding claim 3, Pedersen discloses the claimed invention including the radius of curvature except for the radius being 15% to 30% less than the height of the disk. It would have been obvious to one having ordinary skill in the art at the time the invention was made to design the disk with the appropriate ratios for the purpose of providing the necessary joint space corresponding to the size of the joint, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

16. Regarding claim 4, Pedersen disclosed that the radius of curvature of transition surfaces between said toroidal surface and said convex spherical surfaces is between about 0.7 and about 3 mm (2mm-60mm, paragraph 52).

17. Regarding claim 5, Pedersen disclosed that the radii of curvature of said pair of convex spherical surfaces are the same (symmetrical, paragraph 34).

18. Regarding claim 6, Pedersen discloses the claimed invention including the radius of curvature of the convex surfaces and a peripheral rim is a segment of a sphere (figure 14) except for the radius of the convex surface being twice the radius of the circular disk. It would have been obvious to one having ordinary skill in the art at the time the invention was made to design the disk with the radius of the surface being twice that of the disk for the purpose of accommodating the degree of damage of the native cartilage of the joint and space available within the joint in the individual

(paragraph 49) since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

19. Claims 7 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pedersen (PG Pub No. 20030093152) in further view of Farling (4055862) in further view of Calandruccio (5743918) in further view of Trumble et al. (Thumb Trapeziometacarpal Joint Arthritis: Partial Trapeziectomy With Ligament Reconstruction and Interposition Costochondral Allograft, The Journal of Hand Surgery / Vol. 25A No. 1 January 2000). Trumble et al. and Calandruccio disclose and teach the method steps while Pedersen and Farling disclose the structure of disk of claim 1 (see claim 1). Calandruccio teaches resecting the base of the metacarpus 21 (via small cutting tool 31, figure 3) and the distal surface of the trapezium (via small cutting tool 31, figure 3) to provide concave articular surfaces (semispherical cavities, column 2 lines 14-16) which match the convex articular surfaces of the disk 87 (spherical prosthesis, figure 12). Trumble et al. teaches creating passageways in the metacarpus and the trapezium opening into said articular surfaces (via first and second drill holes, page 63, figure 8) and surgically implanting the implant (carved allograft spacer, figure 8). It would have been obvious to one of ordinary skill in the art at the time of the invention to include the resection of Calandruccio and passageways of Trumble et al. for the purpose of providing an implant that is surrounded by bone at its ends but free in its center to enable joint movement (column 2 lines 23-28) and for the purpose of stabilizing the implant in the joint via tendon graft (page 62).

20. Regarding claim 8, Pedersen teaches an implant that includes the step of selecting said implant to be implanted from a set of said implants of different sizes but all having substantially the same radius of curvature of said convex surfaces (paragraphs 50-52).

21. Claims 11, 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pedersen (PG Pub No. 20030093152).

22. Regarding claim 11, Pedersen discloses the claimed invention including the radius of curvature except for the radius being 15% to 30% less than the height of the disk. It would have been obvious to one having ordinary skill in the art at the time the invention was made to design the disk with the appropriate ratios for the purpose of providing the necessary joint space corresponding to the size of the joint, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

23. Regarding claim 14, Pedersen discloses the claimed invention including the radius of curvature of the convex surfaces and a peripheral rim is a segment of a sphere (figure 14) except for the radius of the convex surface being twice the radius of the circular disk. It would have been obvious to one having ordinary skill in the art at the time the invention was made to design the disk with the radius of the surface being twice that of the disk for the purpose of accommodating the degree of damage of the native cartilage of the joint and space available within the joint in the individual (paragraph 49) since it has been held that where the general conditions of a claim are

disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

24. Claims 15-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pedersen (PG Pub No. 20030093152) in further view of Calandruccio (5743918) in further view of Trumble et al. (Thumb Trapeziometacarpal Joint Arthritis: Partial Trapeziectomy With Ligament Reconstruction and Interposition Costochondral Allograft, The Journal of Hand Surgery / Vol. 25A No. 1 January 2000).

25. Regarding claims 15-16, see claim 6 for further explanation.

26. Regarding claim 17, Pedersen teaches an implant that includes the step of selecting said implant to be implanted from a set of said implants of different sizes but all having substantially the same radius of curvature of said convex surfaces (paragraphs 50-52).

27. Regarding claim 18, Trumble et al. teaches the step of passing a flexible cord (FCR tendon, page 63) through the passageway created in the metacarpus (via wires, page 64, figure 7), the axial opening and the passageway created (via wires, page 64, figure 7) in the trapezium so that the flexible cord conforms to the surface of the axial hole in the plane of flexion when each bone slides on the respective mating surface of the disk.

28. Regarding claims 19-20, Trumble et al. teaches wherein said flexible chord is a harvested tendon (FCR tendon, page 63) and said tendon is harvested from the vicinity of the CMC joint where it remains attached (see figure 8) and the free end is passed through said passageways and tied off or knotted.(sutured to itself, page 64).

Conclusion

29. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JOSHUA LEVINE whose telephone number is (571)270-5413. The examiner can normally be reached on Monday-Thursday 7:30am-5:00pm ETA.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Isabella can be reached on 571-272-4749. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/JOSHUA LEVINE/
Examiner, Art Unit 3774

/Corrine M McDermott/
Supervisory Patent Examiner, Art Unit 3738